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| 10/615,528 | 07/08/2003 | Raymond E. Ideker | 5656-31 | 8193 |
| 20792 7590 02/06/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | EXAMINER REIDEL, JESSICA L | |
| | | | ART UNIT 3766 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | | MAIL DATE | DELIVERY MODE |
| 3 MONTHS | | | 02/06/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/615,528

Applicant(s)

IDEKER, RAYMOND E.

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32,36,55-67,71,72 and 91-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-32,36,55-67,71,72 and 91-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 and 20 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on November 20, 2006. Claims 1-19, 33-35, 37-54, 68-70 and 73-90 have been cancelled. Claims 20-32, 36, 55-67, 71-72 and 91-107 are pending.

Drawings

2. In view of the response filed November 20, 2006, the objections made to the Drawings in the Office Action of August 15, 2006 have been withdrawn.

Claim Objections

3. In view of the response filed November 20, 2006, the Claim Objections made in the Office Action of August 15, 2006 have been withdrawn.

Allowable Subject Matter

4. The indicated allowability of claims 21, 36, 55-58, 60-61, 72, 91-94, 96-100 and 102-107 is withdrawn in view of the newly discovered reference(s) to Sippensgroenewegen (U.S. 2001/0056289) and Narayan et al. (U.S. 7,123,954) (herein Narayan). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 62-67 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner is unable to find support throughout Applicant's disclosure for a system that comprises all three of the following: means for determining a refractory period associated with the heart using premature stimulation, *and* means for determining an activation recovery interval measurement associated with the heart *and* means for determining a Monophasic activation potential (MAP) reading of the heart. Since Claims 63-67 and 71 depend from Claim 62, the deficiencies of Claim 62 are imputed to all dependent claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-32, 36, 55-61, 72, 92-103 and 106-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Sippensgroenewegen. As to Claims 21, 27, 36, 55-56 and 72, Sippensgroenewegen expressly discloses a method and system for localizing and/or treating arrhythmias of a patient's heart and thusly reducing an occurrence of fibrillation (by ablating) (see Sippensgroenewegen Abstract) comprising means for detecting a premature contraction of the heart for a plurality of heart beats characterized by at least one of normal heartbeat activity, premature heartbeat activity or paroxysmal fibrillation, read as nonsustained tachycardia activity for either the atria or ventricles and means for applying an electrical stimulus (i.e. ablation electrical energy) to a region of the heart that is likely/determined to contain a fastest activating region 108 (i.e. an ectopic or focal origin) using a distal electrode pair of catheter 110 (see

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Sippensgroenewegen pages 3-5, paragraphs 19-20 and 39-51 and page 7, paragraphs 68-75).

Sippensgroenewegen specifies that the fastest activating region of the heart 108 is determined by inducing fibrillation of the heart and determining a monophasic activation potential (MAP) reading associated with the fibrillating heart (see Sippensgroenewegen page 1, paragraph 7, page 5, paragraphs 51 and pages 6-8).

9. As to Claims 92, 98 and 106-107, and in addition to the arguments previously presented, Sippensgroenewegen expressly discloses a kit, read as computer program product 120 comprising a computer readable medium having computer readable program code embodied thereon for executing the method as discussed above (see Sippensgroenewegen Fig. 10 and page 8, paragraphs 76-80).

10. As to Claims 22, 28, 57, 93 and 99, the Examiner takes the position that the fastest activating region(s) (either atrial or ventricular) determined by Sippensgroenewegen inherently comprise a reentrant region having a refractory period that is less than areas adjacent to the reentrant region since this is a physiological characteristic of fibrillation mechanisms of the heart. The Examiner supplies Huang et al. (*Regional Differences in Ventricular Fibrillation in the Open-Chest Porcine Left Ventricle*. Circ. Res. 2002; 733-740) (herein Huang) as evidence for this inherency. Huang specifically teaches that a fastest activating region contains a stable reentrant circuit called a mother rotor, which has a shorter refractory period than the remainder epicardial tissue (see Huang page 733).

11. As to Claims 24, 30, 59, 95 and 101, the Examiner takes the position that a reentrant circuit is synonymous with a closed pathway on the heart since the definition of "circuit" is a closed pathway.

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12. As to Claims 25-26, 31-32, 60-61, 96-97 and 102-103, the Examiner takes the position that a "mother rotor" as well known in the art is synonymous with a wave front that propagates along a reentrant circuit (i.e. closed pathway) from a starting point to an ending point that are adjacent to each other as in a circle or reentrant loop.

13. As to Claims 23, 29, 58, 94 and 100, Sippensgroenewegen inherently comprise the limitations of the claims. The Examiner takes the position that a mother rotor is synonymous with a fastest activating region's first wave front. The Examiner also takes the position that mother rotors spawn daughter rotors, which is a physiological characteristic of fibrillation mechanisms of the heart with Huang supplied as evidence. Huang specifically teaches that a mother rotor spawns wavefronts that propagate to maintain ventricular fibrillation elsewhere or other than the location of the fastest activating region's mother rotor (see Huang pages 733-740).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sippensgroenewegen. Sippensgroenewegen discloses the claimed invention but does not expressly disclose that the fastest activating region be determined by determining a refractory period associated with the fibrillating heart using premature stimulation or by determining an activation recovery interval measurement associated with the fibrillating heart. It would have been an obvious matter of design choice to one having ordinary skill in the art to modify the

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system/method or computer readable medium as taught by Sippensgroenewegen to include the steps of/means for/instructions for determining a refractory period associated with the fibrillating heart using premature stimulation or determining an activation recovery interval measurement associated with the fibrillating heart in order to determine a fastest activating region of the heart, because Applicant has not disclosed that determining a refractory period associated with the fibrillating heart using premature stimulation or determining an activation recovery interval measurement associated with the fibrillating heart in order to determine a fastest activating region of the heart provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the MAP technique as taught by Sippensgroenewegen, because it provides a means for locating reentrant circuits or fastest activating regions and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Sippensgroenewegen.

Therefore, it would have been an obvious matter of design choice to modify Sippensgroenewegen to obtain the invention as specified in the claims. In the alternative, it would have been obvious to one having ordinary skill in the art to modify Sippensgroenewegen with steps of/means for/instructions for determining a refractory period associated with the fibrillating heart using premature stimulation or determining an activation recovery interval measurement associated with the fibrillating heart in order to determine a fastest activating region of the heart since both methods are well known in the art as admitted by Applicant at page 11, lines 20-31 of Applicant's disclosure.

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16. Claims 20 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sippensgroenewegen in view of Narayan. Sippensgroenewegen discloses the claimed invention as discussed above except that it is not specified that the electrical stimulus that is applied to the fastest activating region be either a defibrillation stimulus or a pacing stimulus. Narayan, however, teaches that in addition to ablating a determined fastest activating region, pacing/defibrillating can be accomplished by placing leads close to regions of the heart determined to contain the fastest activating region (see Narayan column 3, lines 5-25). Narayan further specifies that placing a lead close to the fastest activating region (i.e. an arrhythmia circuit) makes it easier to terminate that arrhythmia by pacing or defibrillation (see Narayan column 5, lines 45-61 and column 9, lines 5-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify/utilize the method/system of Sippensgroenewegen to place pacing/defibrillation leads adjacent to or close to regions of the heart determined to contain a fastest activating region since such a modification would improve the invention as taught by Narayan.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Steiner et al. (U.S. 5,868,680) teaches a method for monitoring activation patterns from electrogram signals to determine a fastest activating region of a heart and thusly activate a defibrillation device.


Bardy et al. (U.s. 5,129,392) teaches the use of inducing fibrillation to determine the optimal time to deliver therapy relative to the refractory period of a patient's heart.

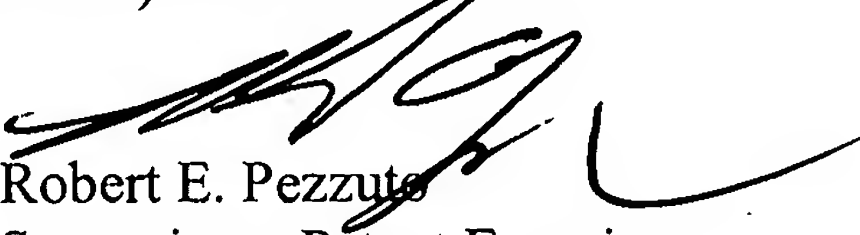
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18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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